

**NOTIFICATION PURSUANT TO**  
**SECTION 6 OF DSHEA**

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of Schiff® *Pregnenolone* Product #12824 bearing the statements set out below. JUN 23 P2:14

**Weider Nutrition International., Inc.**  
**2002 South 5070 West**  
**Salt Lake City, Utah 84104**

The text of each structure-function claim for **Pregnenolone 50 mg per serving** is as follows:

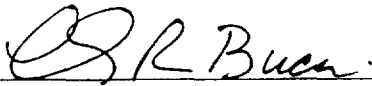
- (Statement 1)** Pregnenolone is manufacture by many tissues (especially adrenal glands, brain, and skin ) from cholesterol. Pregnenolone is a hormone similar to DHEA. Under certain conditions, pregnenolone can be converted into similar substances, such as DHEA or progesterone.
- (Statement 2)** Pregnenolone has been studies since the 1940s. Human and animal studies have found virtually no adverse side effects after pregnenolone supplementation, even after very high doses for long time periods.
- (Statement 3)** Pregnenolone has been called a brain neurosteriod, since brain tissues contain high levels. Pregnenolone supplementation has been associated with maintaining positive sleep patterns in humans, and improved memory and cognitive thinking in animals. Studies from the University of Massachusetts found better performance in healthy, young subjects on flight simulators. Users report improved mood.
- (Statement 4)** Like DHEA, pregnenolone appears to maintain the body's resistance to stress, which has important implications for many body systems.
- (Statement 5)** Pregnenolone appears to assist the body in maintaining balance of many hormones and tissue responses, and to be a precursor to other hormones if they are deficient.
- (Statement 6)** Pregnenolone represents a safe, nature-identical means to assist a positive response to stresses of many kinds.

- (Statement 7) Pregnenolone is a dietary supplement designed to promote moods and mental balance between body systems. Pregnenolone is a hormone similar to DHEA (dehydroepiandrosterone) and may be taken in addition to DHEA, or as an alternative. Pregnenolone is manufactured by many body tissue and under certain conditions, may be converted into similar substances, such as DHEA or progesterone.
- (Statement 8) Pregnenolone is a dietary supplement designed to promote mood and mental balance between body systems.
- (Statement 9) Pregnenolone is manufactured by many body tissues and under certain conditions, may be converted into similar substances, such as DHEA or progesterone.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 3rd day of June, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:   
DR. LUKE R. BUCCI  
Vice President of Research

## STRUCTURE / FUNCTION CLAIMS P2:14

### NUTRIENT: Pregnenolone

DATE: April 9, 1998  
Document Name: sf03preg.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Schiff 12824 Pregnenolone (30t)

NUTRIENT AMOUNT: 50 mg pregnenolone per tablet

STRUCTURE/FUNCTION CLAIM:

Insert:

### SCHIFF® PREGNENOLONE

(3- $\alpha$ -Hydroxy-5- $\beta$ -Pregnen-20-one)

- Pregnenolone is manufactured by many tissues (especially adrenal glands, brain, and skin) from cholesterol. Pregnenolone is a hormone similar to DHEA. Under certain conditions, pregnenolone can be converted into similar substances, such as DHEA or progesterone.
- Pregnenolone has been studied since the 1940s. Human and animal studies have found virtually no adverse side effects after pregnenolone supplementation, even after very high doses for long time periods.
- Pregnenolone has been called a brain neurosteroid, since brain tissues contain high levels. Pregnenolone supplementation has been associated with maintaining positive sleep patterns in humans, and improved memory and cognitive thinking in animals. Studies from the University of Massachusetts found better performance in healthy, young subjects on flight simulators. Users report improved mood.
- Like DHEA, pregnenolone appears to maintain the body's resistance to stress, which has important implications for many body systems.
- Pregnenolone appears to assist the body in maintaining balance of many hormones and tissue responses, and to be a precursor to other hormones if they are deficient.
- Pregnenolone represents a safe, nature-identical means to assist a positive response to stresses of many kinds.

Box:

Pregnenolone is a dietary supplement designed to promote mood and mental balance between body systems. Pregnenolone is a hormone similar to DHEA (dehydroepiandrosterone) and may

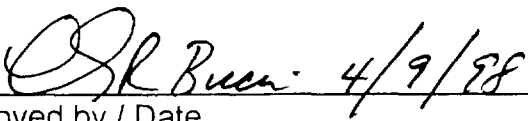
be taken in addition to DHEA, or as an alternative. Pregnenolone is manufactured by many body tissues and under certain conditions, may be converted into similar substances, such as DHEA or progesterone.

**Bottle:**

Pregnenolone is a dietary supplement designed to promote mood and mental balance between body systems.

Pregnenolone is manufactured by many body tissues and under certain conditions, may be converted into similar substances, such as DHEA or progesterone.

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Approved by / Date

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